

censed by law to administer such drug, and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 12-14-56. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5202. Hoxsey treatment for internal cancer. (Inj. No. 311.) *See also* N. J. No. 5212 in this supplement.

COMPLAINT FOR INJUNCTION FILED: 5-28-57, W. Dist. Pa., against Hoxsey Cancer Clinic, a corporation, Portage, Pa., John J. Haluska, president and administrator, Philip Stager, treasurer, Samuel Einhorn, secretary, John H. Benko, vice president, and Delmar Randall and Harold Galbraith, osteopathic physicians employed by the corporation.

An amended complaint was filed on 8-22-57.

ACCOMPANYING LABELING: Booklet entitled "What is Cancer? How Does It Function?"; pamphlet entitled "Procedure and Information, Hoxsey Cancer Clinic, Inc."; miscellaneous reprints of articles and letters written and distributed by John J. Haluska; monthly publication entitled "Globe Gazette"; and book entitled "The Pittsburgh Trial."

NATURE OF DRUGS: The original complaint alleged that the essential part of the *Hoxsey treatment for internal cancer* was either a combination of green and red tablets or a combination of yellow and red tablets.

The complaint alleged also that the green tablets were composed of licorice, burdock root, stillingia root, berberis root, pokeroot, cascara sagrada, prickly ash bark, buckthorn bark, and red clover; that the yellow tablets were composed of red clover, buckthorn bark, stillingia root, berberis root, pokeroot, and pepsin; and that the red tablets were composed of potassium iodide.

The complaint alleged further that at times the potassium iodide was furnished as a liquid solution or omitted entirely.

METHOD OF OPERATION: The original complaint alleged that a typical method used by the defendants in the promotion, sale, and distribution of the treatment, in interstate commerce, was as follows: Interest in the treatment was promoted by articles appearing in the *Globe Gazette*, edited by John J. Haluska, and by articles published in the *Defender* magazine, edited by Gerald B. Winrod. In response to an inquiry concerning the treatment, from a person living outside Pennsylvania, an invitation to visit the clinic was issued in a letter bearing the facsimile signature of defendant Harold L. Galbraith as medical director of the clinic. When the prospective out-of-state customer arrived on the premises of the clinic, he was interviewed by the employees, at which time there was a discussion of his symptoms and ailments. This was followed by laboratory tests of the blood and urine, X-rays, and a physical examination of the customer. On that basis, the prospective customer's condition was diagnosed as cancer without a biopsy. The customer then was sold the *Hoxsey treatment for internal cancer*, comprised essentially of the above-described tablets, and the treatment was delivered to the customer for transportation outside Pennsylvania.

On 8-22-57, the complaint was amended to include the allegation that, upon entry of the temporary restraining order as described below, the defendants did the following: With no notice to the persons going to the

*See also No. 5201.

clinic for the Hoxsey treatment, and without changing the labeling representations and suggestions that they were distributing the *Hoxsey treatment for internal cancer* in man, the defendants discontinued the delivery of the above-described combinations of pills, which were, as the defendants had admitted, the essential part of the *Hoxsey treatment for internal cancer* in man. In substitution, the defendants delivered to people going to the clinic from outside Pennsylvania a group of simple medications— usually brewer's yeast tablets, ascorbic acid (vitamin C) tablets, antacid tablets, laxative tablets, and pain pills—previously given as supportive treatment for the cancer medicines; and, in lieu of the above combinations of tablets, the clinic gave a prescription for a saturated solution of potassium iodide, to be filled by an outside pharmacy.

CHARGE: The original complaint alleged that the defendants were engaged in promoting, selling, distributing, and causing to be introduced and delivered for introduction into interstate commerce the so-called *Hoxsey treatment for internal cancer*, the essential part of which consisted of the combination of green and red tablets or the combination of yellow and red tablets. It was alleged also that when the tablets were caused to be introduced and delivered into interstate commerce, the tablets were misbranded as follows:

502 (a)—the tablets were accompanied by the above labeling, which falsely represented and suggested that the *Hoxsey treatment for internal cancer* was an adequate and effective treatment for internal cancer in man;

502 (f) (1)—at times, no labeling accompanied the tablets, in which case the labeling of the tablets failed to bear adequate directions for use in that their labeling failed to state that the tablets were intended for the treatment of cancer;

502 (f) (1)—with or without the above labeling, the tablets failed to bear labeling stating adequate directions for use in that the directions as to dosage and frequency and duration of administration were not adequate for the treatment for which the tablets were intended, namely, cancer, since the tablets were worthless for the treatment of cancer and adequate directions could not be given for the use of the above-described tablets in the treatment of cancer.

The original complaint alleged also that the *Hoxsey treatment for internal cancer* had been adjudged worthless for the treatment of cancer in man on two previous occasions resulting in: (a) a decree of permanent injunction, dated 10-26-53, issued by the United States District Court for the Northern District of Texas (see D. D. N. J. No. 4654) and (b) a decree of condemnation, pursuant to a jury verdict rendered on 11-16-56, in the United States District Court for the Western District of Pennsylvania (see D. D. N. J. No. 5212); that the defendants were in privity with the persons bound by the two judgments and were themselves bound by them and precluded by the two judgments from denying that the Hoxsey treatment was inadequate and ineffective in the treatment of internal cancer in man; that the corporate defendant was the successor to the Hoxsey Cancer Clinic, claimant in the seizure case, which the individual defendants, Haluska, Stager, Einhorn, and Benko, together with Newton C. Allen, operated from the time it opened until it was succeeded by the corporation; that the individual defendants were financially interested in the clinic and obtained profits from it; and, therefore, the defendants were aware and bound by the above judgments and knew their activities were violative of the Act.

The amended complaint charged that the defendants, after the entry of the temporary restraining order, caused to be introduced and delivered for introduction into interstate commerce the substitute drugs which were misbranded under 502 (a) :

(1) in that the labeling represented and suggested that such drugs comprised the *Hoxsey treatment for internal cancer*, whereas the essential part of the treatment had been discontinued ; and

(2) in that the labeling failed to state the material fact that the Hoxsey Cancer Clinic no longer distributed or delivered to out-of-state patients with cancer the tablets that comprised the essential part of the Hoxsey cancer treatment.

DISPOSITION: On 5-28-57, the court issued a temporary restraining order enjoining the defendants against the commission of the acts complained of. By agreement of the parties, the temporary restraining order was extended on 6-19-57 until trial on the issues. The defendants filed their answers to the complaint on 7-15-57.

A pretrial conference was held on 8-22-57, at which time the court entered an order amending the complaint to include the additional charges above. Also, the Government moved for inclusion of the testimony of certain witnesses who had testified in the above-mentioned seizure case in the trial on the issues in this case. It was the opinion of the court that an order from the United States Court of Appeals for the Third Circuit was necessary before the testimony could be so incorporated, inasmuch as the seizure case (see D. D. N. J. No. 5212) was being appealed to the court of appeals at that time.

Accordingly, the Government filed a motion in the United States Court of Appeals for the Third Circuit for an order to permit the United States District Court for the Western District of Pennsylvania to incorporate such testimony in the instant case. The motion was granted by the court of appeals on 9-4-57.

On 9-6-57, the district court entered the following order :

MEMORANDUM ORDER

GOUBLEY, *Chief Judge*: "It appears in this proceeding after pre-trial conference that substantial dispute exists between the parties as to the legal effect of the adjudication of Civil Action No. 13251, which involved the same parties, and as to the intent of Judge Miller in his adjudication of the many matters that were presented to him that justice would be best served if the proceeding would be heard by the same judge who administered and adjudicated the trial of the companion proceeding.

NOW, THEREFORE, this 6th day of September, 1957, the within proceeding is assigned to the Honorable John L. Miller for trial on the 23rd day of September, 1957, and all matters relative thereto shall be presented to said member of the court for consideration, determination and adjudication."

The case came on for trial on 9-23-57. On 10-2-57, at the conclusion of the Government's case, the court entered the following consent decree of permanent injunction :

MILLER, *District Judge*: "The plaintiff's complaint praying for a permanent injunction having come on for hearing and the testimony of the plaintiff having been taken, the defendants indicated a desire to consent to the entry of a decree of permanent injunction in the manner and form prayed for by the plaintiff.

"IT IS THEREFORE ORDERED that the defendants, Hoxsey Cancer Clinic, Inc., a corporation, and John J. Haluska, Philip Stager, Samuel Ein-

horn, John H. Benko, Delmar Randall, and Harold Galbraith, individuals, and their officers, agents, servants, employees, representatives, and all other persons in active concert or participation with them or any of them, be and they are hereby perpetually enjoined and restrained from directly or indirectly, introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, and more particularly delivering or causing to be delivered to any patient or customer living outside the Commonwealth of Pennsylvania for transportation in interstate commerce, in violation of Section 301 (a) of said Act (21 U. S. C. 331 (a)), the articles of drug known as the Hoxsey treatment for internal cancer, and any other articles of drug, the labeling of which represents or suggests that the said drugs comprise the Hoxsey treatment for internal cancer in man, and any other drug or similar composition which—

(a) are accompanied by the aforesaid labeling, namely, the booklet entitled, "What is Cancer? How Does it Function?" a pamphlet entitled, Procedure and Information. Hoxsey Cancer Clinic, Inc., miscellaneous reprints of articles and letters written and distributed by John J. Haluska, a monthly publication entitled the "Globe Gazette," and a book entitled, "The Pittsburgh Trial," devoted substantially to the promotion of the Hoxsey treatment;

(b) are represented or suggested in their labeling to be adequate and effective in the treatment of cancer in man;

(c) are misbranded within the meaning of Section 502 (a) of the Act (21 U. S. C. 352 (a)) by reason of any false or misleading representations or suggestions in the labeling of such drugs;

(d) are misbranded within the meaning of Section 502 (f) (1) of the Act (21 U. S. C. 352 (f) (1)) by reason of the failure of the labeling of said articles to bear adequate directions for use because of the omission from said labeling of a statement of the condition or disease, namely, cancer, which said articles are intended to treat or prevent, and because the directions as to how to take the medicines are not adequate for the condition for which the said medicines are intended."

5203. Nutrilite food supplement. (F. D. C. No. 37261. S. Nos. 88-421 L, 88-430 L.)

INFORMATION FILED: 9-30-55, W. Dist. N. Y., against John Josef and Elinor M. F. Josef, Rochester, N. Y.

ALLEGED VIOLATION: In the course of a sales talk given at Rochester, N. Y., on 9-24-54, Elinor M. F. Josef made oral representations holding the article out to the persons present as an effective treatment for diabetes, cancer, multiple sclerosis, nervousness, arthritis, psoriasis, and malaria; and in the course of sales talks given at Rochester, N. Y., on 9-28-54, John Josef and Elinor M. F. Josef made additional oral representations holding the articles out to the persons present as an effective treatment for multiple sclerosis, diabetes, psoriasis, arthritis, muscular dystrophy, nervousness, paralysis, cerebral palsy, ulcerated stomach, neuritis, pyorrhea, high blood pressure, bad eyesight, alcoholism, nervous breakdown, rheumatism, heart trouble, amyotrophic lateral sclerosis, hypertension, facial flushes, headaches, dizziness, and a letdown feeling.

The acts of the defendants in making such oral representations resulted in the article being misbranded while held for sale after shipment in interstate commerce.

LABEL IN PART: (Pkg.) "Nutrilite (R) XX [or "Junior"] Food Supplement
This package contains multiple vitamin capsules and mineral tablets for use as a dietary food supplement to fortify, or supplement, the diet."

CHARGE: 502 (f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions